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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,562	03/31/2004	Mohamed Zaiou	15670-076001 / 2002-119	5767

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EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 09/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/815,562	MOHAMED ZAIOU	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I Claims 1 and 11-18, drawn to an isolated cationic cathelin-like peptide having antimicrobial activity, comprising an amino acid sequence of SEQ ID NO: 3 or fragment thereof; a pharmaceutical composition comprising a peptide selected from the group consisting of (a) a peptide comprising a sequence of SEQ ID NO: 3, and (b) a peptide comprising a sequence as set forth in SEQ ID NO: 2 from about amino acid 31-131, in a pharmaceutically acceptable carrier; classified in class 530, subclass 350; class 514, subclass 2.

The claims in Group I contain reference to patentably distinct and/or independent peptides, see claims 1, 11 and 12(a) for each of X 1 through X 31 in SEQ ID NO: 3. Should Group I be elected, applicant is required to select one residue to define the "X" in the sequence of SEQ ID NO: 3 in claims 1, 11 and 12(a); or select one sequence by SEQ ID NO: 2 (e.g., claim 12 (b)). Any change of amino acid residue at any one or more positions in the sequence is considered, absent factual data to the contrary, a distinct peptide. Because the peptides are considered patentably distinct, this is **not** a species election.

Group II Claim 2, drawn to an isolated polynucleotide that encodes a polypeptide of claim 1; classified in class 536, subclass 23.1, 23.5; class 435, subclass 69.1.

The claim in Group II contains reference to patentably distinct and/or independent peptides, see claim 1 for each of X 1 through X 31 in SEQ ID NO: 3. Should Group II be elected, applicant is required to select one residue to define the sequence of SEQ ID NO: 3 in claim 1. Any change of amino acid residue at any one or more positions in the sequence is considered, absent factual data to the contrary, a distinct peptide. Because the peptides encoded by the polynucleotides are considered patentably distinct, this is **not** a species election.

Group III Claims 3-10, drawn to a method for inhibiting the growth of a bacterium or yeast comprising contacting the bacterium or yeast with a peptide with antimicrobial activity, comprising an amino acid sequence selected from the group consisting of (a) an amino acid sequence of SEQ ID NO: 3, and (b) an amino acid sequence of SEQ ID NO: 2 from about amino acid 31-131; classified in class 530, subclass 350; class 514, subclass 2.

The claims in Group III contain reference to patentably distinct and/or independent peptides, see claim 3 for each of X 1 through X 31 in SEQ ID NO: 3. Should Group III be elected, applicant is required to select one residue to define the sequence of SEQ ID NO: 3 in claim 3; or select one sequence by SEQ ID NO: 2 (e.g., claim 3 (b)). Any change of amino acid residue at any one or more positions in the sequence is considered, absent factual data to the contrary, a

distinct peptide. Because the peptides used in the method are considered patentably distinct, this is **not** a species election.

Group IV Claims 19 and 20, drawn to a method of alleviating symptoms of a bacterial infection in a subject, comprising administering an N-terminal active fragment of a cathelicidine-derived peptide comprising an amino acid sequence of SEQ ID NO: 2; or a peptide comprising a sequence of SEQ ID NO: 3; classified in class 530, subclass 350; class 514, subclass 2, 44.

The claims in Group IV contain reference to patentably distinct and/or independent peptides, see claim 19 for each of X 1 through X 31 in SEQ ID NO: 3. Should Group IV be elected, applicant is required to select one sequence by SEQ ID NO: 2 or one residue to define the sequence of SEQ ID NO: 3 in claim 19; or. Any change of amino acid residue at any one or more positions in the sequence is considered, absent factual data to the contrary, a distinct peptide. Because the peptides used in the method are considered patentably distinct, this is **not** a species election.

Group V Claim 21, drawn to a method for promoting tissue repair and regeneration in a subject comprising contacting an injured tissue with a composition comprising a peptide selected from the group consisting of: (a) a peptide comprising an amino acid sequence of SEQ ID NO: 3, and (b) and a peptide comprising an amino acid

sequence of SEQ ID NO: 2 from about amino acid 31-131; classified in class 530, subclass 350; class 514, subclass 2, 44.

The claim in Group V contains reference to patentably distinct and/or independent peptides, see claim 21 for each of X 1 through X 31 in SEQ ID NO: 3. Should Group V be elected, applicant is required to select one residue to define the sequence of SEQ ID NO: 3 in claim 21; or select one sequence by SEQ ID NO: 2. Any change of amino acid residue at any one or more positions in the sequence is considered, absent factual data to the contrary, a distinct peptide. Because the peptides used in the method are considered patentably distinct, this is **not** a species election.

Inventions in Group I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP ' 806.04, MPEP ' 808.01). In the instant case the polypeptide of Group I and the polynucleotide of Group II differ with respect to their structure, and their physical, chemical and biological properties and function. The peptides of Group I can be used to make antibodies, while polynucleotides of Group II can be used for hybridization assay. Therefore, the inventions are patentably distinct.

Inventions in Group I and Groups III/IV/V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP ' 806.05(h)). In the instant case the claimed polypeptide of Group I can be used in a materially different process of making specific antibodies. Therefore, the inventions are patentably distinct.

Inventions in Group II and Groups III/IV/V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP ' 806.04, MPEP ' 808.01). In the instant case the polynucleotide of Group II is a separate and distinct chemical entity and has different function from the polypeptide of Groups III/IV/V and is not used in the methods of Groups III/IV/V. The polynucleotide of Group II can be used for hybridization assay while the methods in Groups III/IV/V use peptides of Group I. Therefore, the inventions are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re*

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita Mitra whose telephone number is 571-272-0954. The examiner can normally be reached on M-F, 10:00 am-7:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained

from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JON WEBER
SUPERVISORY PATENT EXAMINER

Rita Mitra, Ph.D.
September 20, 2005